

## **REMARKS**

### **A. Claim Amendments**

Claims 1, 2 and 7-9 were considered in the Office Action mailed on January 6, 2010.

Claim 1 has been amended to incorporate the limitations of dependent claim 2, and to specify that the lubricating composition contains minimal free water. Claim 1 has been further amended to recite that when the condom is engaged on the genitalia of a male user, the lubricating composition warms upon contact with free water from the user's bodily secretions to provide him with a warming sensation. Support for these amendments can be found at least in the claims as originally filed; at page 2, lines 20-22; and at page 4, Table 1 of the specification as originally filed. In addition, claim 2 has been canceled and claim 7 has been amended to correct dependency.

New claims 10-15 have been added. Support for new claims 10 and 13 can be found at least at page 2, line 5, of the specification as originally filed. Support for new claim 11 can be found at least at page 1, lines 13-15; page 2, lines 20-23; and page 6, lines 1-3, of the specification as originally filed. Support for new claim 13 can be found at least in claim 4 as originally filed. Finally, support for new claims 14 and 15 can be found at least at page 2, lines 9-12, of the specification as originally filed.

No new matter has been introduced by the amendments made herein. Applicants have amended the claims solely to expedite prosecution of this application. In making these amendments, Applicants are not conceding or acquiescing to the pending rejections or abandoning or surrendering any of the subject matter in previous versions or listing of the claims or in the application. Accordingly, Applicants reserve the right to pursue claims of similar, different, narrower, or broader scope in the future.

In view of the amendments to the claims and the following remarks, Applicants respectfully request reconsideration and withdrawal of the rejections.

**B. Rejection Under 35 USC § 103(a) Over Harrison et al., US2002/0103414**

In the Office Action of January 6, 2010, claims 1, 2, 8 and 9 were rejected under 35 USC § 103(a) as allegedly being obvious over Harrison et al., U.S. Patent Application Publication No. US2002/0103414 (“Harrison”). Applicants respectfully traverse the rejection below with respect to currently pending claims 1, 8 and 9.

The device of Applicants’ invention, as claimed, is a packaged condom comprising a tubular sheath for engaging the genitalia of a male user, and a lubricating composition that warms upon contact with free water from bodily secretions of the male user, thereby providing the user with a warming sensation. According to independent claim 1, the lubricating composition is located on at least a portion of the inner and outer surfaces of the sheath. Claim 1 further recites that the lubricating composition comprises two or more glycols and minimal free water, and includes glyceryl polymethacrylate, at least about 10% w/w propylene glycol, and at least about 30% w/w polyethylene glycol, wherein the amount of polyethylene glycol is greater than the amount of propylene glycol.

In direct contrast with Applicants’ claimed invention, which provides user with a specific sensation — a warming sensation — the device of Harrison operates to desensitize the genitalia of the user. Harrison reports a condom comprising a sheath together with two distinct lubricants: a first lubricating composition comprising a desensitizing agent for use on the inner surface of the sheath (referred to throughout Harrison as a “first lubricating composition”); and a second lubricating composition that does not comprise a desensitizing agent for use on the outer surface of the sheath (referred to throughout Harrison as a “second lubricating composition”). As disclosed by Harrison, the desensitizing agent is used on the inner surface of the sheath to reduce the sensitivity of the genitalia of the male user in a manner effective to prevent premature ejaculation. (See, e.g., paragraph 0018.) According to Harrison, the first lubricating composition must have a relatively high viscosity so that it remains substantially in place during storage and use. This is to ensure that the desensitizing agent is contained on the inner surface in contact with the male genitalia, and kept separated from the outer surface to avoid desensitization of the female genitalia (e.g., a sexual partner of the condom user) (See paragraph 0006.)

In rejecting Applicants' claims under § 103(a), the Examiner asserts that Harrison teaches a condom with lubrication, "wherein the lubrication comprises 44% or 68.2% propylene glycol... While there is no disclosure that the lubricant is a warmth inducing lubricant as presently claimed [by Applicants], given that Harrison et al. disclose lubrication composition identical to that claimed and comprising propylene glycol in amounts claimed, it is clear that the lubricating composition would inherently warm upon contact with compositions containing free water." (See Office Action at pages 4-5, emphasis added.) The Examiner further asserts that Harrison teaches propylene glycol used with polyethylene glycol but acknowledges Harrison is silent with regard to the concentration of polyethylene glycol. However, the Examiner states that "it has been shown that absent a showing of criticality with respect to 'concentration of polyethylene glycol' (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the 'concentration of polyethylene glycol' through routine experimentation to values, including those presently claimed in order to achieve 'an effective lubricant'. It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA, 1980)." (See Office Action at page 5.)

As provided in MPEP § 2141, to formulate a determination of obviousness under 35 USC § 103, the Examiner must (A) determine the scope and content of the prior art; (B) ascertain the differences between the claimed invention and the prior art; and (C) resolve the level of skill in the art. In determining the differences between the claimed invention and the prior art, the Examiner must consider the claimed invention *as a whole*. The question "is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." (MPEP § 2141.02, emphasis in the original.) In addition, a prior art reference must "be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." (MPEP § 2141.02, emphasis in the original.) The recently- published 2010 KSR Guidelines Update stresses that nonobviousness arguments based teaching away from the claimed invention by prior art still apply, and "[i]ndeed, they may have even taken on added importance in view of [KSR]." (Fed. Reg. Vol. 75, No. 169 (Sept. 1, 2010, page 536545).

As an initial matter, Applicants respectfully submit that in formulating this rejection, the Examiner has considered neither Applicants' claimed invention nor the prior art as a whole. Rather, the Examiner appears to have considered particular elements of Applicants' claimed device in isolation, without regard to the structural and functional incorporation of these elements into Applicants' claimed invention as a whole. Furthermore, with respect to the lubricating composition of Applicants' claimed invention, the Examiner has addressed it on a nearly component-by-component basis without consideration to the composition as a whole. In doing so, the Examiner appears to have taken bits and pieces of the prior art without consideration of the teachings of the prior art reference as a whole.

In support of the rejection under § 103 over Harrison, the Examiner asserts two main premises: (1) Harrison discloses an identical lubricating composition which inherently must warm upon contact with free water; and (2) Harrison discloses each of the individual components of the Applicants' lubricating composition and each of these individual components is a results-effective variable that one skilled in the art would have optimized to produce "an effective lubricant". While these assertions are addressed separately below, Applicants respectfully submit that Applicants' claimed invention, *when considered as a whole*, is not obvious in view of Harrison, *when considered as a whole*. Applicants' claimed device requires a warmth-inducing lubricating composition on the inner surface of the sheath. The intended purpose of Applicants' claimed device is to provide the male condom user with a pleasant and positive sensation for an enhanced sexual experience. As currently claimed, the lubricating composition which is located on the inner surface of the sheath must warm upon contact with free water from the user's bodily secretion, and must provide the user with a warming sensation — i.e., a warmth that must be sensed by the user. In contrast, the entirety of the Harrison disclosure is focused on a device that requires a desensitizing lubricating composition on the inner surface of the sheath. The intended purpose of the Harrison device is to desensitize, i.e., to lessen or eliminate sensation in the genitalia of the user to prevent premature ejaculation. Harrison expressly teaches that only a lubricating composition comprising a desensitizing agent is suitable for use on the inner surface of the sheath. Considered in whole, Harrison teaches away from Applicants' claimed invention because modifying the device of Harrison by providing a warmth-inducing lubricating composition

without a desensitizing agent on the inner surface of the sheath would render the device entirely unsatisfactory for its intended use. This is as true for newly-added claims 10-15, as it is for rejected claims 1 and 7-9.

Notwithstanding the foregoing, Applicants address below each of the Examiner's main premises asserted in support of the rejection of claims 1 and 8 under § 103 over Harrison.

**1. *The Harrison Composition Is Not Inherently Warmth-Inducing***

According to MPEP § 2112, to rely on an inherent disclosure of a claim limitation in the prior art, the Examiner must provide a rationale or evidence tending to show inherency. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill...' *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)." (MPEP § 2112, emphasis added.) Furthermore "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)."

By way of rationale, the Examiner offers only the statement that "given that Harrison et al. disclose lubrication composition identical to that claimed and comprising propylene glycol in amounts claimed, it is clear that the lubricating composition would inherently warm upon contact with compositions containing free water." (See Office Action at page 5.) Contrary to the Examiner's assertion, Applicants respectfully submit that while Harrison discloses various lubricant components that may be suitable for use in a lubricating composition, Harrison fails to disclose any lubricating composition that is identical in formula and function to the lubricating composition recited by Applicants' claims.

As discussed above, the device of Harrison comprises a sheath together with two distinct lubricating compositions: a "first lubricating composition" with a desensitizing agent for use on the inner surface of the sheath; and a "second lubricating composition" without a

desensitizing agent for use on the outer surface of the sheath. (See paragraph 0006.) Harrison provides little guidance on formulating a first or a second lubricating composition. With respect to the first lubricating composition, Harrison discloses that the lubricant components are selected to provide a relatively high viscosity to the composition. (See paragraph 0020.) Harrison further provides that “it is desirable that the lubricant [component] be able to solubilize the desensitizing agent to provide uniform distribution of the same over the inner surface of the condom.” (See paragraphs 0020 and 0021.) Harrison also discloses certain suitable desensitizing agents, including the preferred desensitizing agent benzocaine. (See paragraph 0018.) In addition, Harrison discloses that the lubricant components that may be effectively employed in either the first or second lubricating composition “could include but are not limited to glycols (e.g., polyethylene glycols, propylene glycol), water-based gels (e.g., glyceryl polymethacrylate, carboxymethyl cellulose), silicone-based oil and gels, mineral oils, and so forth.” (See paragraphs 0020, 0021, and 0024.) Notably, Harrison provides no teaching or suggestion whatsoever regarding any advantage in the avoidance or minimization of free water in formulating a first or second lubricating composition. Quite to the contrary, Harrison includes water-based gels among the list of suitable components for the first and second lubricating compositions.

As for actual lubricating compositions, Harrison discloses only two formulas. At Table 1, Harrison discloses a first lubricating composition, which is for use only on the inner surface of the sheath and has the following formula:

**TABLE 1**

Propylene Glycol	44.0% w/w
Polyethylene Glycol 400	15.0% w/w
Mixture of Glyceryl Polymethacrylate, Propylene Glycol and Water	35.0% w/w
Benzocaine USP	6.0% w/w

At Table 2, Harrison discloses a second lubricating composition, which is for use only on the outer surface of the sheath and has the following formula:

**TABLE 2**

Propylene Glycol	68.2% w/w
Polyethylene Glycol 400	6.8% w/w
Mixture of Glyceryl Polymethacrylate, Propylene Glycol and Water	25.0% w/w

While both of these compositions comprise at least 10% propylene glycol, neither composition comprises at least 30% w/w polyethylene glycol, as required by claim 1 of the instant application. The first lubricating composition comprises only one-half the required amount of polyethylene glycol, and the second composition requires less than one-quarter the required amount. Furthermore, neither composition comprises an amount of polyethylene glycol that is more than the amount of propylene glycol, as required by claim 1. From a mathematical perspective, the second lubricating composition, with 68.2% w/w propylene glycol, could not meet this limitation even if the composition also comprised at least 30% w/w polyethylene glycol.

Notwithstanding the fact that the neither of the above formulas meets all of the limitations recited by Applicants' claimed invention, Applicants respectfully submit that it is in fact only the so-called "first lubricating compositions" of Harrison that have any relevancy to the consideration of the warmth-inducing property of the lubricant recited by Applicants' claims. Applicants' claims, as amended, expressly require that when the sheath is engaged on the genitalia of a male user, the lubricating composition warms upon contact with free water from the bodily secretions of the user to provide a warming sensation to the user — i.e., it is the lubricating composition on the inner surface that mixes with the male user's bodily secretions on the interior of the engaged sheath so as to provide the user with a warming sensation. Harrison explicitly teaches that the inner surface of the sheath must be coated with a "first

lubricating composition”, which comprises a desensitizing agent. Harrison explicitly discloses that the second lubricating composition “is applied only to exterior surface of the condom”. (See paragraph 0022). Further, Harrison teaches away from using the second lubricating composition on the inner surface of the sheath because doing so would render the device of Harrison wholly unsuitable for its intended purpose — i.e., to provide a desensitizing agent to the genitalia of male user in order to prevent premature ejaculation. (See, e.g., paragraphs 0006 and 0018.) Accordingly, Harrison teaches away from the use of a so-called “second lubricating composition”, as provided in Table 2, on the inner surface of a sheath.

Contrary to the Examiner’s assertion, Applicants respectfully submit that the relevant lubricating compositions disclosed by Harrison would not inherently warm upon contact with compositions containing free water, and even if it did, the desensitizing agent of the first lubricating composition of Harrison would negate any sensation of warmth by the user. According to Applicants’ invention and as described in Applicants’ specification at page 2, lines 4-7, the lubricating composition must have minimal or no free water in order to produce a warming effect upon contact with free water derived from the bodily secretions of the user. This effect is a factor of the change in the total enthalpy of the solution upon mixing. More specifically, it is due to the heat of hydration that is produced when the glycols are mixed with water and heat is evolved in an exothermic reaction, primarily as a result of hydration of the glycols by hydrogen bond formation.<sup>1</sup>

The lubricating composition disclosed in Table 1 of Harrison comprises benzocaine as a desensitizing agent. Benzocaine is poorly soluble in water, but is soluble in polyethylene glycol and other glycols, as well as other solvents.<sup>2</sup> Upon solubilization, benzocaine is known

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<sup>1</sup> See Rowe et al., “Molecular Weight Dependence of the Heats of Hydration of Some Oligomeric Ethylene Oxides and Their Methoxyl Derivatives”, J. Applied Polymer Science, Vol. 50, 321-326 (1993) at page 321. A copy of this reference is submitted herewith along with an Information Disclosure Statement.

<sup>2</sup> See Rubino et al., “Cosolvency and Deviations from Log-Linear Solubilization”, Pharma. Res., Vol. 4, No. 3, 231-236 (1987) at page 235; Rytting et al., “A Quantitative Structure-Property Relationship for Predicting Drug Solubility in PEG 400/Water Cosolvent Systems”, Pharm. Res. Vol. 21, No. 2 (Feb. 2004) at page 237. Rubino et al., “Cosolvency and Cosolvent Polarity”, Pharma. Res., Vol. 4, No. 3 (1987) at page 220. Copies of these references are submitted herewith along with an Information Disclosure Statement.



to form hydrogen bonds with the solvent and, when in a cosolvent-water mixture, to compete with water for the hydrogen bonding sites on the cosolvent.<sup>3</sup>

Harrison discloses the preparation of the first lubricating composition in Example 1. According to Harrison, the benzocaine was solubilized in a solution comprising propylene glycol, polyethylene glycol and Lubrajel® CG by mixing the benzocaine with the solution for a minimum of four hours at a temperature of between 75 °C and 80 °C. (See paragraphs 0029-0031.) Upon solubilization, benzocaine would form hydrogen bonds at the hydrogen bonding sites of the glycols in the lubricant solution, making those sites unavailable for hydrogen bonding with free water. As such, the lubricating composition of Harrison would not necessarily warm upon contact with free water because, under ambient conditions, the free water would not be able to form hydrogen bonds with the glycols in a manner so as to result in an overall exothermic reaction — i.e., there would be little or no heat of hydration generated. Accordingly, the lubricating composition disclosed by Harrison does not inherently warm upon contact with free water.

## ***2. Optimization of Component Concentrations Would Not Have Been Obvious***

As noted above, Applicants respectfully submit that among the limitations of Applicants' claims that are not taught or suggested by Harrison is the requirement that the lubricating composition comprises at least 30% w/w polyethylene glycol. While the Examiner acknowledges that Harrison is silent with regard to the concentration of polyethylene glycol being at least 30% w/w, the Examiner asserts that "it has been shown that absent a showing of criticality with respect to 'concentration of polyethylene glycol' (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the 'concentration of polyethylene glycol' through routine experimentation to values, including those presently claimed in order to achieve 'an effective lubricant'. It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)." (See Office Action at page 5.)

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<sup>3</sup> See Avila et al., "Thermodynamic Study of the Solubility of Benzocaine in Some Organic and Aqueous Solvents", J. of Solution Chemistry, Vol. 31, No. 12, 975-985 (2002); Rubino et al, supra, at page 230; Rytting et al., supra, at page 237.

According to MPEP § 2144.05 IIB only a particular parameter that is first recognized in the prior art as a result-effective variable can be optimized by routine experimentation. In *In re Antonie*, 559 F.2d 618, 195 USPQ 6, (1997), the Court addressed the obviousness of a claim drawn to a wastewater treatment device having a specified tank volume-to-contractor area ratio to maximize efficiency. The claim stood rejected by the Patent and Trademark Office on the basis that the basic device was taught by the prior art and working out the value for optimum efficiency would be mere mechanical experimentation. The Court found that the prior art did not recognize that treatment capacity was a function of the tank volume-to-contractor area ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable. According to the Court, “[r]ecognition of this functionality is essential to the obviousness of conducting experiments to determine the value of the ‘tank volume’ ratio which will maximize treatment capacity.” The Court stated that the sort of experiments required to determine the functionality would not have been suggested by the teachings of the prior art reference since the reference was not trying to maximize or control “treatment capacity”. According to the Court, “[t]he experiments suggest by [the prior art reference] do not reveal the property which applicant has discovered, and the PTO has provided us with no other basis for the obviousness of the necessary experiments.”

As in *Antonie*, Harrison does not recognize the concentration of polyethylene glycol as a result-effective variable and does not suggest the sort of experiments required to optimize the weight percentage of polyethylene glycol for the purpose of providing a warmth-imparting lubricating composition. As the Examiner must recognize, the weight percentage of polyethylene glycol cannot be optimized as a single component of a composition. Rather, optimization of the polyethylene glycol in the composition of Harrison would require one to determine how to concurrently modify the weight percentages of propylene glycol, glyceryl polymethacrylate, water, and/or benzocaine to account for 100% of the composition by weight. Harrison provides no suggestion of the additional experiments that would be required to make such a determination.

Furthermore, contrary to the Examiner’s assertion, the disclosure of Harrison is focused on more than achieving “an effective lubricant” for use on the inner surface of condom.

Harrison is focused on providing a condom having a lubricating composition capable of desensitizing the male user's genitalia in a manner effective to prevent premature ejaculation. The teachings of Harrison do not reveal the potential warming properties provided by the polyethylene glycol as part of the lubricating composition on the inner surface of the condom, as claimed in the present application. According to the teachings of Harrison, an effective lubricant for use on the inner surface of a condom requires a desensitizing agent such as benzocaine, and a relatively high viscosity. The very presence of polyethylene glycol, let alone the percentage of polyethylene glycol, is not recognized as a results-effective variable with respect to achieving an effective lubricating composition for the inner surface of a condom within the disclosure of Harrison. In fact, Harrison does not suggest any particular benefit to the use of glycols in the lubricating compositions, but rather includes them in a list of other lubricant components that may be effectively employed in the lubricating compositions, which also includes "water-based gels (e.g. glyceryl polymethacrylate, carboxymethyl cellulose), silicone-based oils and gels, mineral oils, and so forth." (See paragraph 0021.) The very mention of water-based gels underscores the lack of recognition for a warmth-inducing effect that is generated by the lubricant of Applicants' claimed invention, which expressly requires minimal free water. One simply would not be motivated in view of Harrison's disclosure to optimize the percentage of polyethylene glycol (and, consequently, other components of the composition) for that result.

In rejecting claims 8 and 9, the Examiner took a similar position with respect to glyceryl polymethacrylate, polypropylene glycol and water. (See the Office Action at pages 5 and 6.) Inasmuch as Applicants' claims recite propylene glycol rather than polypropylene glycol, Applicants assume that the Examiner intended to refer to propylene glycol. Applicants respectfully submit that for the same reasons provided above, these components were not recognized in Harrison as result-effective variables and one skilled in the art would not have been motivated by the teachings of Harrison to optimize them to arrive at Applicants' claimed invention.

For the reasons discussed above, Applicants respectfully submit that Harrison does not teach or suggest a device comprising a lubricating composition located on the inner surface of a sheath which comprises at least 10% propylene glycol, at least 30% polyethylene glycol, and

minimal or no free water, wherein the amount of polyethylene glycol is greater than the amount of propylene glycol, and wherein when the device is in use with the sheath engaged on the genitalia of a male user, the lubricating composition warms upon contact with free water from the user's bodily secretions to provide a warming sensation to the user. Accordingly, Harrison fails to teach or suggest, either explicitly or implicitly, all of the limitations of Applicants' claim 1, or dependent claims 8 and 9. Accordingly, Applicants respectfully request that the rejection of claims 1, 8 and 9 under 35 USC § 103 over Harrison be reconsidered and withdrawn.

**C. Rejection Under 35 U.S.C. § 103 Over Harrison in view of Ahmad et al., US2003/0211161**

In the Office Action of January 6, 2010, claim 7 was rejected under 35 USC § 103(a) as allegedly being unpatentable over Harrison in view of Ahmad et al., U.S. Patent Application Publication No. US2003/0211161 ("Ahmad"). Claim 7 is dependent from claim 1 and adds the further limitation that the lubricating composition includes at least about 5% w/w glycerin. As discussed above, Harrison fails to teach or suggest all of the limitations of base claim 1 and those deficiencies are not remedied by Ahmad. As such, Applicants respectfully submit that claim 7 is not rendered obvious by Harrison even in view of Ahmad.

Furthermore, Applicants submit that even if all of the limitations of claim 7 were disclosed by the combination of Harrison with Ahmad, the references themselves teach away from the combination. Ahmad teaches warming lubricating compositions especially for use on vaginal or oral mucosa, and as a treatment for female sexual dysfunction. (See Ahmad at, e.g., paragraphs 0002, 0023, 0025, 0045, 0048, 0059, 0060, 0070). Ahmad fails to teach or suggest the use of warming lubricating compositions in connection with normal female sexual activity. Furthermore, Ahmad completely fails to teach or suggest the use of a warming lubricating composition on male genitalia, on a device to be used or engaged on male genitalia, or in connection with male sexual activity.

The very focus of Harrison on providing a condom with a desensitizing agent to desensitize the genitalia of a male user in an manner effective to prevent premature ejaculation teaches away from the modification of Harrison to provide instead a condom with a warming lubricating composition — a modification intended to provide a positive sensation that would likely be

counterproductive in preventing premature ejaculation. (See MPEP § 2143.01 V, “[i]f a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F. 2d 90, 221 USPQ 1125 (Fed. Cir. 1984).” Further, according to MPEP § 2143.01 VI, “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F. 2d 810, 123 USPQ 349 (CCPA 1959).”) Because Harrison’s principle of operation is the inclusion of a desensitizing agent, the modification to include a warming lubricating composition would change the principle of operation so much so as to render the Harrison device unsatisfactory for its intended use.

For the reasons provided above, Harrison and Ahmad are not properly combinable, and even if combined, fail to teach or suggest all of the limitations of Applicants’ claim 7. Accordingly, Applicants respectfully request that the rejection of claim 7 under 35 USC § 103(a) over Harrison in view of Ahmad be reconsidered and withdrawn.

**D. Rejection for Double Patenting; Statement of Common Ownership**

In the Office Action of January 6, 2010, claims 1, 2 and 9 were rejected for nonstatutory obviousness-type double patenting over claims 1-2 and 6-9 of Harrison et al., U.S. Patent No. 7,086,403 (“the ‘403 patent”). Applicants note that the ‘403 patent issued from the Harrison et al. application which was published as U.S. Application Publication No. US 2002/0103414, referred to above as “Harrison” in connection with the rejections under 35 USC § 103. Applicants respectfully traverse the rejection below with respect to the currently pending claims 1 and 9.

For the same reasons as discussed above with respect to Harrison, the ‘403 patent does not teach or suggest teach or suggest a device, as claimed by Applicants, which comprises a lubricating composition located on the inner surface of a sheath which comprises at least 10% propylene glycol, at least 30% polyethylene glycol, and minimal or no free water, wherein the amount of polyethylene glycol is greater than the amount of propylene glycol, and wherein when the device is in use with the sheath engaged on the genitalia of a male user, the lubricating composition warms upon contact with free water in the user’s bodily secretions to

provide a warming sensation to the user. As such, Applicants submit that claim 1 and 9 are patentably distinct over the claims issued on the '403 patent.

In addition, at page 3 of the Office Action, the Examiner states that the claims 1-6 and 9 are "directed to an invention not patentably distinct from claim 1, 2, and 1-9 of commonly assigned 7,086,483". Applicants assume that the Examiner intended to refer to claims 1, 2 and 9 of the instant application inasmuch as claims 3-6 were previously canceled. Applicants further assume that Examiner intended to refer to U.S. Patent No. 7,086,403. Applicants kindly request that the Examiner correct the Applicants' assumptions, if needed. In any event, as provided under MPEP § 706.02(1)(2), to disqualify the '403 patent as prior art, the undersigned Attorney of Record submits the following statement as evidence of common ownership of the instant patent application and U.S. Patent No. 7,086,403 at the time the invention of this application was made:

#### **STATEMENT OF COMMON OWNERSHIP**

U.S. Patent Application No. 10/598,366 and U.S. Patent No. 7,086,403 were, at the time the invention of U.S. Patent Application No. 10/598,366 was made, owned by Armkel LLC.

Applicants note that Armkel LLC has since been acquired by Church & Dwight Co., Inc., the current common owner of both U.S. Patent Application No. 10/598,366 and U.S. Patent No. 7,086,403. For the reasons provided herein, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 9 for non-statutory obviousness-type double patenting over U.S. Pat. No. 7,086,403; and submit that the U.S. Pat. No. 7,086,403 has been disqualified as prior art under 35 USC § 102(e), (f), or (g), thereby precluding any future rejection under 35 USC § 103(a) based on that patent.

## **CONCLUSION**

In view of the foregoing, it is respectfully submitted that this application is now in condition for allowance. For the reasons detailed herein, Applicants respectfully request that all rejections be reconsidered and withdrawn, and that the claims be passed into allowance. Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to contact Applicants' representative by telephone at the number indicated below.

Respectfully submitted,

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